



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2017-C-6238]

Listing of Color Additives Exempt From Certification; Calcium Carbonate; Confirmation of Effective Date

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of October 28, 2022, for the final rule that appeared in the *Federal Register* of September 27, 2022, and that amended the color additive regulations to provide for the safe use of calcium carbonate in dietary supplement tablets and capsules.

DATES: Effective date of final rule published in the *Federal Register* of September 27, 2022 (87 FR 58445) confirmed: October 28, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christopher Kampmeyer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1255.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 27, 2022 (87 FR 58445), we amended the color additive regulations in § 73.70 (21 CFR 73.70) “Calcium Carbonate” by expanding the permitted uses of calcium carbonate to include use in dietary

supplement tablets and capsules, including coatings and printing inks, in amounts consistent with good manufacturing practice.

We gave interested persons until October 27, 2022, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. We received a comment requesting a revision to the regulation that would account for a possible change to the standard of identity for chocolate. We note, however, that the rule already contains language to allow the use of calcium carbonate if the standard of identity for chocolate changes in the future, and that the rule's text is more precise than that requested by the comment because "added color" (21 CFR 73.70(c)) refers back to calcium carbonate only, whereas the comment's suggested change could be interpreted as covering additional color additives. Therefore, we find that the effective date of the final rule that published in the *Federal Register* of September 27, 2022, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Incorporation by reference, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the September 27, 2022, final rule. Accordingly, the amendments issued thereby became effective October 28, 2022.

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.